

## **REMARKS**

### **A. Terminal Disclaimer**

Without admission of double patenting, enclosed is a terminal disclaimer with respect to U.S. Patent No. 6,513,530 and U.S. Patent No. 6,250,307.

### **B. U.S. Patent No. 5,181,505 to Lew et. Al. ("Lew '505")**

Lew '505 does not teach an implant. The item 10, 10', 10'' is placed in the mouth between the tongue and the palate. It touches but is not embedded within the mucosa. See, Lew '505, Col. 4, lines 7 – 12.

Lew '505 obstructs the airway requiring a tube 40 to permit breathing.

The intent of Lew '505 is a temporary device in the mouth for drug delivery.

### **C. U.S. Patent No. 6,098,629 to Johnson et al. ("Johnson '629")**

Johnson '629 places a bulking device (see Fig. 2) in the tissue of the esophagus at the lower esophageal sphincter (LES). The intent is to add bulk to the LES to prevent gastroesophageal reflux disease (GERD).

The esophagus is the lumen for transporting food and drink to the stomach. It is not part of the airway. Therefore, it cannot anticipate airway treatments.

In Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 77 U.S.P.Q. 2d 1321 (Fed. Cir. 2005), the Court reversed a finding of anticipation as to method claims directed to treating or preventing skin damage (sunburn) using an old lotion described in the prior art for cosmetic use on skin. The district court had concluded that a single prior art reference (Pereira) anticipated certain of the claims of one of the patents in suit (i.e., the '693 patent). Pereira disclosed cosmetic compositions for topical applications. The district court found anticipation because the compositions of Pereira included all the various ingredients in the concentrations claimed in the '693 patent. The district court concluded the topical application of the prior art compositions would necessarily yield the claimed skin benefits of the '693 patent.

The Court upheld an anticipation finding as to claims 8 – 13 of the '693 patent. These claims merely required application of the composition to exposed skin surface. On the other hand, claims 1 – 4 and 7 recited application of a composition to "skin sunburn". The Court reversed the anticipation finding as to these claims.

Claim 1 of the '693 patent, from which claims 2-4 and 7 ultimately depend, specifically recites application of the fatty acid ester to "skin sunburn." This claim term raises a different problem. The issue is not, as the dissent and district court imply, whether Pereira's lotion *if applied* to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in *Catalina Marketing International, Inc. v. Cool Savings.com, Inc.* that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. New uses of old products or processes are indeed patentable subject matter. *See* 35 U.S.C. § 101 (2000) (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); *In re King* (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well.

Claim 1 of the '693 patent recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn. In other words, the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application *to skin sunburn*, this court reverses the district court's holding that Pereira anticipates claims 1-4 and 7 of the '693 patent.

432 F.3d at 1328, 77 U.S.P.Q. 2d at 1378 (citations omitted, italicization original, underlining added).

#### **D. Amendments**

The independent claims are amended to recite the implant is imbedded within tissue of the airway without obstructing the airway. Neither reference shows or suggests these features in combination with the other features of the claims.

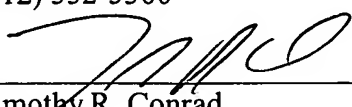
**E. Conclusion**

Applicants respectfully submit this application is now in condition for allowance.  
Reconsideration and notice of allowance are solicited.

Respectfully submitted,

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